



## OraSure Announces 2015 Third Quarter Financial Results

November 4, 2015

BETHLEHEM, Pa., Nov. 04, 2015 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ:OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the three and nine months ended September 30, 2015.

### Financial Highlights

- Consolidated net revenues for the third quarter of 2015 were \$29.9 million, a 7% increase from the comparable quarter of 2014. Consolidated net revenues for the nine months ended September 30, 2015 were \$87.3 million, a 12% increase from the comparable period of 2014.
- The Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), contributed \$7.3 million in net revenues during the third quarter of 2015, which represents a 7% increase over the third quarter of 2014. Net revenues from this segment for the nine months ended September 30, 2015 were \$22.1 million, a 26% increase from the comparable period in 2014.
- Net domestic revenues from sales of the Company's OraQuick<sup>®</sup> rapid HCV test were \$1.9 million for the third quarter of 2015, representing a 47% increase over the third quarter of 2014 and 13% sequential growth from the second quarter of 2015. Net domestic product revenues for this product were \$4.8 million for the nine months ended September 30, 2015, a 51% increase from the comparable period in 2014. Total HCV-related revenues, including exclusivity payments recognized under the HCV co-promotion agreement with AbbVie, were \$6.3 million and \$17.5 million for the third quarter and nine months of 2015, respectively, as compared to \$5.2 million and \$9.7 million for the third quarter and nine months of 2014, respectively.
- Consolidated net income for the third quarter of 2015 was \$1.5 million, or \$0.03 per share on a fully-diluted basis, which compares to consolidated net income of \$1.1 million, or \$0.02 per share on a fully-diluted basis, for the third quarter of 2014. Consolidated net income for the nine months ended September 30, 2015 was \$3.6 million, or \$0.06 per share on a fully-diluted basis, which compares to a consolidated net loss of \$2.0 million, or \$0.04 per share, for the comparable period of 2014. The Company's bottom line results for the nine months of 2014 included a \$5.5 million payment received as a result of the termination of the Company's drug assay collaboration with Roche Diagnostics, which was recorded as an offset to expenses in the second quarter of 2014.
- Cash and short-term investments totaled \$108.2 million and working capital amounted to \$112.1 million at September 30, 2015.

"We are pleased with the Company's financial results for the third quarter," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our molecular collection systems segment continued its solid performance with a second consecutive quarter of more than \$7 million in revenues. In addition, our HCV business once again generated strong quarterly growth on both a year-over-year basis and sequentially when compared to the second quarter of this year. We expect these businesses will continue to be the primary growth drivers for our Company."

### Financial Results

Consolidated net product revenues for the third quarter and first nine months of 2015 increased 5% and 3% over the comparable periods of 2014, respectively, primarily as a result of higher sales of the Company's molecular collection systems, OraQuick<sup>®</sup> HCV and Intercept<sup>®</sup> products. These increases were partially offset by lower OraQuick<sup>®</sup> professional HIV product sales in both periods and lower cryosurgical systems sales during the nine-month period.

Consolidated other revenues for the third quarter and first nine months of 2015 were \$4.1 million and \$11.5 million, respectively. Other revenues in the current quarter included \$3.4 million of exclusivity payments recognized under the Company's HCV co-promotion agreement with AbbVie and \$750,000 of Ebola-related funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA"). Other revenue in the first nine months of 2015 included \$10.0 million of AbbVie exclusivity payments and \$1.5 million in BARDA funding. Other revenues in the third quarter and first nine months of 2014 included \$3.4 million and \$4.2 million of AbbVie exclusivity payments, respectively.

Consolidated gross margin for the three and nine months ended September 30, 2015 was 69% and 67%, respectively. Consolidated gross margin for the three and nine months ended September 30, 2014 was 67% and 63%, respectively. Gross margin for the current quarter increased primarily due to a reduction in royalty expense and the increase in other revenues, partially offset by the impact of a less favorable product mix. Gross margin for the nine-month period improved largely due to the \$7.4 million increase in other revenues and a reduction in royalty expense. Other revenues contributed

approximately 500 and 200 basis points to gross margin for the nine months ended September 30, 2015 and 2014, respectively.

Consolidated operating expenses increased to \$19.1 million during the third quarter of 2015 compared to \$17.8 million in the comparable period of 2014. This increase was largely due to costs associated with the AbbVie co-promotion agreement along with higher legal costs, partially offset by lower research and development expenses and a favorable change in the exchange rate between the Canadian and U.S. dollar.

For the nine months ended September 30, 2015, consolidated operating expenses were \$54.4 million, an increase from the \$50.9 million reported for the nine months ended September 30, 2014. This increase was largely due to the absence of the \$5.5 million Roche termination payment received in 2014, higher legal costs, increased research and development expenses, and costs associated with the AbbVie co-promotion agreement, partially offset by lower promotional expenses for the Company's OraQuick® In-Home HIV test and the impact of a favorable change in exchange rates. Promotional expenses for the OraQuick® In-Home HIV test were \$1.3 million and \$7.7 million for the first nine months of 2015 and 2014, respectively.

The Company's cash and short-term investment balance totaled \$108.2 million at September 30, 2015 compared to \$97.9 million at December 31, 2014. Working capital was \$112.1 million at September 30, 2015 compared to \$104.8 million at December 31, 2014. For the nine months ended September 30, 2015, the Company generated \$15.1 million in cash from operations.

#### Fourth Quarter 2015 Outlook

The Company expects consolidated net revenues to range from \$29.5 to \$30.0 million and is projecting a consolidated net income of between \$0.03 and \$0.04 per share.

#### Financial Data

##### Condensed Consolidated Financial Data

(In thousands, except per-share data)

##### Unaudited

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
<b>Results of Operations</b>				
Net revenues	\$ 29,861	\$ 27,845	\$ 87,337	\$ 77,783
Cost of products sold	9,192	9,140	28,974	29,135
Gross profit	20,669	18,705	58,363	48,648
Operating expenses:				
Research and development	2,525	2,990	8,961	8,242
Sales and marketing	9,677	9,216	26,465	30,828
General and administrative	6,931	5,617	18,971	17,317
Gain on contract termination	-	-	-	(5,500 )
Total operating expenses	19,133	17,823	54,397	50,887
Operating income (loss)	1,536	882	3,966	(2,239 )
Other income	81	268	395	244
Income (loss) before income taxes	1,617	1,150	4,361	(1,995 )
Income tax expense (benefit)	147	10	810	(33 )
Net income (loss)	\$ 1,470	\$ 1,140	\$ 3,551	\$ (1,962 )
Earnings (loss) per share:				
Basic	\$ 0.03	\$ 0.02	\$ 0.06	\$ (0.04 )
Diluted	\$ 0.03	\$ 0.02	\$ 0.06	\$ (0.04 )
Weighted average shares:				
Basic	56,482	56,018	56,427	55,897
Diluted	56,692	56,666	56,900	55,897

#### Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,			Percentage of	
	Dollars			Total Net	
				Revenues	
<u>Market</u>	2015	2014	% Change	2015	2014

Infectious disease testing	\$ 11,297	\$ 11,183	1	%	38	%	40	%
Substance abuse testing	2,955	2,149	38		10		8	
Cryosurgical systems	3,458	3,241	7		11		11	
Molecular collection systems	7,329	6,867	7		25		25	
Insurance risk assessment	675	1,007	(33	)	2		4	
Net product revenues	25,714	24,447	5		86		88	
Other	4,147	3,398	22		14		12	
Net revenues	\$ 29,861	\$ 27,845	7	%	100	%	100	%

**Nine Months Ended September 30,**

	Dollars			Percentage of Total Net Revenues			
<u>Market</u>	2015	2014	% Change	2015		2014	
Infectious disease testing	\$ 34,585	\$ 34,914	(1 )%	40	%	45	%
Substance abuse testing	7,584	6,187	23	9		8	
Cryosurgical systems	8,956	12,128	(26 )	10		15	
Molecular collection systems	22,148	17,523	26	25		23	
Insurance risk assessment	2,519	2,858	(12 )	3		4	
Net product revenues	75,792	73,610	3	87		95	
Other	11,545	4,173	177	13		5	
Net revenues	\$ 87,337	\$ 77,783	12 %	100 %		100 %	

<b>HIV Revenues</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>	<b>2015</b>	<b>2014</b>	<b>% Change</b>
Domestic	\$ 5,548	\$ 7,231	(23 )%	\$ 18,147	\$ 21,568	(16 )%
International	450	491	(8 )	1,995	1,897	5
Domestic OTC	1,642	1,368	20	4,923	4,991	(1 )
Net product revenues	\$ 7,640	\$ 9,090	(16 )%	\$ 25,065	\$ 28,456	(12 )%

<b>HCV Revenues</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>	<b>2015</b>	<b>2014</b>	<b>% Change</b>
Domestic	\$ 1,914	\$ 1,301	47 %	\$ 4,803	\$ 3,183	51 %
International	957	470	104	2,577	2,341	10
Net product revenues	2,871	1,771	62	7,380	5,524	34
Amortization of exclusivity payments	3,397	3,398	-	10,081	4,173	142
Net HCV-related revenues	\$ 6,268	\$ 5,169	21 %	\$ 17,461	\$ 9,697	80 %

<b>Intercept® Revenues</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>	<b>2015</b>	<b>2014</b>	<b>% Change</b>

Net Intercept® revenues \$ 2,251 \$ 1,606 40 % \$ 5,764 \$ 4,473 29 %

<b><u>Cryosurgical Systems Revenues</u></b>	<b>Three Months Ended</b>			<b>Nine Months Ended</b>		
	<b>September 30,</b>			<b>September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>	<b>2015</b>	<b>2014</b>	<b>% Change</b>
Domestic professional	\$ 1,600	\$ 1,590	1 %	\$ 3,268	\$ 4,601	(29 )%
International professional	258	43	*	757	581	30
Domestic over-the-counter	137	-	*	300	-	*
International over-the-counter	1,463	1,608	(9 )	4,631	6,946	(33 )
Net cryosurgical systems revenues	\$ 3,458	\$ 3,241	7 %	\$ 8,956	\$ 12,128	(26 )%

\* Calculation is not considered meaningful

#### **Condensed Consolidated Balance Sheets (Unaudited)**

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
<b><u>Assets</u></b>		
	\$ 100,677	\$ 92,867
Cash		
Short-term investments	7,512	5,000
Accounts receivable, net	17,089	16,138
Inventories	14,985	15,763
Other current assets	1,559	1,446
Property and equipment, net	17,800	17,934
Intangible assets, net	13,661	17,505
Goodwill	18,974	21,734
Other non-current assets	1,589	1,246
Total assets	\$ 193,846	\$ 189,633

#### **Liabilities and Stockholders' Equity**

Accounts payable	\$ 6,964	\$ 7,148
Deferred revenue	13,302	8,043
Other current liabilities	9,429	11,271
Other non-current liabilities	1,142	1,234
Deferred income taxes	3,010	3,236
Stockholders' equity	159,999	158,701
Total liabilities and stockholders' equity	\$ 193,846	\$ 189,633

	<b>Nine months ended</b>	
	<b>September 30,</b>	
<b>Additional Financial Data (Unaudited)</b>	<b>2015</b>	<b>2014</b>

Capital expenditures	\$ 1,885	\$ 2,353
Depreciation and amortization	\$ 4,259	\$ 4,732
Stock-based compensation	\$ 4,543	\$ 4,284
Cash provided by operating activities	\$ 15,105	\$ 8,384

## Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2015 third quarter financial results, certain business developments and financial guidance for the fourth quarter of 2015, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #52009076 or go to OraSure Technologies' web site, [www.orasure.com](http://www.orasure.com), and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until November 11, 2015, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #52009076.

## About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

## Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; our ability to achieve financial and performance objectives under the HCV co-promotion agreement with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNAG to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2014, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

Ronald H. Spair  
Chief Financial Officer  
610-882-1820  
[Investorinfo@orasure.com](mailto:Investorinfo@orasure.com)  
[www.orasure.com](http://www.orasure.com)



OraSure Technologies, Inc.

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